

**Title of Research Study:** [Enter the title of the research study]

**Principal Investigator:** [Enter the name of the principal investigator]

**Student Investigator:** [If relevant, include the name of the student researcher, especially if the project is conducted by a graduate or undergraduate student as part of a degree or certificate program]

**Supported By:** [Detail all forms of financial and in-kind support for this research. Mention your school or department if there is no external funding] This research receives support from \_\_\_\_\_\_\_\_\_\_\_\_\_.

**Disclosure of Potential Conflicts of Interest:**

[Incorporate this section if a conflict of interest exists. If not, remove it.] This disclosure is provided to allow you to make an informed decision regarding your participation in this study, considering the following conflict of interest: [detail the conflict of interest and the measures implemented to minimize its impact].

[Add this section if the investigator is also the participant’s healthcare provider. Otherwise, eliminate it.] Your physician, who is also leading this research project, [alternatively, if your healthcare provider is overseeing this research study, it should be noted that s/he…] has a dual role in focusing on your health and managing this study. You are entitled to consult with someone outside the research team about the study before making a decision on participation.

**Collaborating Institutions:** [if not relevant, please omit.]

**Essential Information Regarding This Research Study:**

Below is a concise overview of this study to assist you in deciding whether to participate. More comprehensive details are provided further in this document.

* The aim of this study is \_\_\_\_\_.
* Your participation will involve \_\_\_\_\_\_\_\_\_ [insert a succinct description of what will be required of participants. For example: You will need to fill out a questionnaire and participate in a follow-up interview.
* The duration of your involvement in this research is expected to be \_\_\_\_\_\_\_\_ [specify the total time commitment and the number of visits required for the study].
* The primary risk associated with participation is \_\_\_\_\_\_\_.
* The principal advantage of participating in this study is \_\_\_\_\_\_\_.

Should your research employ techniques of deception and/or not fully disclose all aspects from the outset, it is imperative to include a statement here indicating that the information presented in the initial consent is not exhaustive. For appropriate wording, consult the Supplemental Consent Language Document.

If your study constitutes a clinical trial, you are required to furnish details regarding the trial's registration and the dissemination of its results on the ClinicalTrials.gov platform. Refer to the Supplemental Consent Language Document for the precise language needed.

**Why Have You Been Invited to Participate in This Research Study?**

You are being invited to participate in this research study due to \_\_\_\_\_\_\_\_\_\_\_\_\_. [Specify the particular circumstances (e.g., being a student, a parent) or conditions (e.g., age range of 18-45) qualifying participants for the research. Additionally, detail any significant exclusion criteria, where relevant. It is crucial that the inclusion/exclusion criteria outlined in your study protocol document align with the descriptions provided here regarding eligibility for participation in your study.]

**How Many Participants Will Be Involved in This Study?**

It is anticipated that approximately \_\_\_\_\_ individuals will participate in this research study. If the study is to be conducted across multiple institutions, please use the following phrasing: We anticipate enrolling approximately \_\_\_\_\_ individuals through [Indicate the media for participant recruitment], contributing to a total of about \_\_\_\_\_ participants across all institutions involved in this study.

**What Is Important for Me to Understand About Participating in a Research Study?**

* You will receive a thorough explanation of the research study. [Omit if not relevant.]
* The decision to participate is entirely yours.
* You have the option not to participate.
* It's possible to consent to participate and later decide to withdraw.
* Your choice will not negatively impact you.
* You have the liberty to ask any questions before making a decision.
* You are not obligated to respond to any questions you prefer not to answer. [This point should be included for studies involving surveys, interviews, and/or focus groups.]

**What are the implications if I agree to participate in this study?**

Inform participants in straightforward language about what they can anticipate.

Outline the research activities and methods in the order they will happen, mentioning the frequency of these activities and methods. If feasible, provide a visual aid like a diagram or table to illustrate the steps and assessments involved in research that consists of multiple stages or appointments.

* Specify the total time and span of each study visit, activity, and method.
* Identify the individuals with whom the participant will be in contact.
* Detail the timing and location of the research activities.
* Clarify which actions are part of routine or expected practices [for instance, if the research occurs within an educational setting, differentiate between normal educational activities and those conducted for research purposes. If the study involves any clinical treatment, such as mental health services, distinguish between regular treatment and research components].
* When relevant, indicate whether the research involves audio or visual recordings or photography. Provide clarity on whether participation in audio/visual recording/photography is mandatory or optional for involvement in the study.
* [If participants are randomized to comparison groups include the following:] The group of study participants you will be assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose which study group you are assigned to. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being assigned to any given group.

**Will I Receive Any Benefits from Participating in This Study?**

While we cannot guarantee any specific benefits to you or others from your participation in this research, potential advantages may include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Outline the potential benefits of participating in the study. Initially, mention any possible direct benefits to the participant, followed by any potential benefits to others. Remember, financial compensation for participation should not be considered a benefit – details regarding any financial compensation and reimbursements should be provided in the subsequent section titled “Will I be paid or given anything for taking part in this study?”]

**Could Participating in This Study Pose Risks to Me?**

It's important to consider and understand the reasonably foreseeable risks associated with this study. If available, information on the likelihood and severity of these risks will be provided. Possible risks include:

* Physical risks
* Psychological risks
* Risks to your privacy (Note: For studies collecting data from individuals in the European Economic Area, consent and data security measures must adhere to the European Union’s General Data Protection Regulation (GDPR))
* Legal risks
* Social risks
* Economic risks
* Risks of harm to groups or communities

[This paragraph is to be included in the consent form for ALL studies involving the collection of potentially identifiable data:] One potential risk in any research involves the possibility of a breach of confidentiality, meaning that confidential information from the study could be accessed by unauthorized individuals. We are committed to taking all possible measures to minimize this risk, as detailed later in this document.

**What Happens If I Choose Not to Participate or If I Decide to Withdraw Later?**

Participating in this study is completely at your discretion. It is your right to decide whether or not you want to be a part of it. Should you choose at any point to discontinue your participation or withdraw from the study, such a decision will not affect your standing [this includes your grades, position in class, and/or access to healthcare services] with BeyondBound [as well as with any other entities associated with your research study, if applicable].

[If applicable, include alternatives to participation.] If you choose not to take part in this research study, there are other options available to you: [List and describe alternative activities and/or treatments that are generally accessible to a patient or participant.]

If the research is intended to involve participants from student pools: Detail the alternative ways to obtain course credit or fulfill research study criteria without participating in this specific study (for instance, by writing an essay or taking part in another study). These alternatives should align with the options BeyondBound has approved under the guidelines for the student subject pool.

You retain the right to withdraw from the study at any time without facing any negative consequences.

Describe what happens to the data collected up to the point of withdrawal if the participant chooses to leave the study:

* If you withdraw from the study, you will be asked for permission regarding the handling of data that has been collected from you up until that point.

**OR**

* If you decide to withdraw, any data that has been collected up to that point will be discarded.

**How Will My Information Be Protected by the Researchers?**

The research team will implement a variety of procedures to ensure the security and confidentiality of your information. Measures include the use of encryption technology for digital data, storing identifiable information separately from the rest of the research data, and maintaining only de-identified transcripts from interviews or focus groups. For more details on recommended practices for research data security, please visit our website at: [Include a link to the website].

If this study is supported by NIH funding or will apply for a Certificate of Confidentiality, it is necessary to incorporate specific information regarding the protections and limitations that come with the Certificate of Confidentiality. Refer to the Supplemental Consent Language Document for the precise wording to use concerning the Certificate of Confidentiality.

In cases where focus groups are a method of data collection, additional considerations for participant privacy and data confidentiality within the focus group environment must be addressed. Please see the Supplemental Consent Language Document for the appropriate language to include privacy and confidentiality limitations in the context of focus groups.

**Who Will Have Access to the Information Collected During This Research Study?**

We will take measures to restrict the use and disclosure of your personal information, including any records related to this research study, to those who require it for review. However, absolute confidentiality cannot be guaranteed.

Your information may be accessed or used by others beyond the research team during or after the conclusion of this study for various reasons, including:

* University and government officials, study sponsors, auditors, and the Institutional Review Board may need to review the study information to ensure the research is conducted safely and correctly.
* Collaborating researchers at other institutions who are part of this study may have access to the information. [Include this point only if applicable to your study].
* The research team may disclose information to relevant authorities for health and safety reasons – for instance, if there's an indication of intent to harm yourself or others, or for public health purposes. [Include this point only if relevant to your study].

[Include the appropriate statement regarding child abuse or neglect, as per the context of your study and BeyonBound's policy and state law requiring employees to report suspected cases of child abuse and/or neglect.]

If information about child abuse or neglect comes to light, we may be legally or policy-bound to report this to the authorities.

OR

We will not inquire about child abuse, but should you disclose any incidents of child abuse or neglect, we may be required or permitted by law or policy to report it.

If the study might disclose information governed by Federal laws on sexual harassment and sexual violence, include specific consent language about Title IX reporting responsibilities. See the Supplemental Consent Language Document for the exact wording required for Title IX reporting obligations.

[Discuss the disclosure of research assessments, educational or clinically relevant results to participants, including the circumstances under which they will be informed, if applicable.] Most assessments in research are strictly for investigative purposes and lack immediate relevance for [developmental, educational, or healthcare] contexts. If research findings are relevant to your health, the researchers will [will not] notify you about their discoveries.

[If there's a plan to retain data or specimens for future research, explain the storage location, who will have access, and the retention duration for these materials.]

[For studies involving genetic information, refer to the Supplemental Consent Language Document for the Genetic Information Nondiscrimination Act (GINA) to include the mandated language.]

**What are the potential ways in which data gathered from this study could be distributed in the future?**

The details we gather about you during this research will be retained for recordkeeping purposes related to the study [and possibly for inclusion in future research endeavors]. If the data from the study include identifiable information: Your name and any other details that could directly identify you will be securely stored in a manner separate from the rest of the data we collect from you.

For studies that extend over a period (longitudinal studies), note: The research team [intends to/might] reach out to you for further participation in this study.

Data that do not reveal your identity from this study could be shared with the broader research community, including in publications of the study findings, and with databases and repositories utilized for research purposes. [If identifiable information will be collected, add:] Before any study data are shared, we will either remove or encode any personal details that could reveal your identity.

However, we cannot assure complete anonymity of your personal data.

If there is an intention to keep or distribute identifiable data for future research not yet specified, a new application for IRB review must be filed, including a detailed plan, consent forms, and supporting documentation (e.g., research registry). Should the Principal Investigator (PI) wish to offer the possibility of contacting you for future studies they conduct, this information can be provided at the conclusion, incorporating the following: The PI is interested in keeping your contact details to reach out to you for potential future research involvement. This information will be kept confidential and not shared with other investigators, being used solely for possible future research by this PI. Your agreement for this will be requested at the conclusion of this consent form. Participation in this current study does not require your consent for future use of your identifiable data in subsequent research.

[Omit if there are no plans for sharing identifiable data]The outcomes of this study might be disseminated through articles and presentations, but will exclude any personally identifying details unless you expressly consent to the disclosure of such information in these outputs.

**Will I Receive Compensation or Any Other Form of Reimbursement for Participating in This Study?**

For your participation in this research, you will be compensated with [specify the type of compensation, e.g., cash, gift card, check] in the total amount of [specify the total amount of compensation]. Please note the following details regarding compensation if they apply to your study:

* If compensation will be prorated for any reason, such as if a participant decides to withdraw before completing all aspects of the study.
* If there will be any form of bonus payment, or if any portion of the compensation depends on the decisions or performance of the participant or a group of participants.
* In cases where a raffle or lottery is employed as part of compensation, detail the amount and total number of payments to be awarded, the odds of winning (if known), the approximate timing of the drawing, and the method by which winners will be informed.
* If participants will be reimbursed for transportation, parking, or other expenses incurred as a result of participation in this study.
* For studies involving a student subject pool, outline the amount of course credit participants will receive.

Additionally, if participating in the study could incur costs to participants, such as for parking and transportation, please describe those here.

Should there be no compensation or reimbursement for participating in this study, please be informed: There is no payment or reimbursement for participating in this study.

**HIPAA Authorization – Consent to Utilize Personal Health Information for Research Purposes**

[This section is to be included only if HIPAA Authorization is necessary for the study].

[If not required, this section should be omitted.] We pledge to respect your privacy and maintain the confidentiality of your personal information. By agreeing to participate in this study, you are authorizing us to access, use, and disclose your personal health information, which may include information contained within your medical records as well as data that can personally identify you. For instance, personal health information might comprise your name, address, telephone number, or social security number. The types of health information we might collect and utilize for this research encompass: [Adjust the list below to include all types of health information that may be accessed, used, or disclosed for research purposes. Append any additional relevant types of information. Remove any types that are not applicable.]

* Results from physical examinations
* Medical history [Exclude information from mental health notes. If collecting information on mental health or developmental disability services, detail in the subsequent bullet.]
* Laboratory test results, or certain health data indicating or relating to a specific condition as well as diaries and questionnaires
* Information regarding study medication or drugs
* Details concerning study devices
* Billing records
* Results from HIV tests
* Substance Use Disorder information: [Detail specifically.]
* Developmental Disability information: [Detail specifically.]
* Mental Health information: [Detail specifically.]
* Genetic Testing information: [Detail specifically.]

OR

* All Information in a medical record **[Inclusion of “all information in a medical record” necessitates incorporating sensitive information provisions such as the expiration date of the consent, the right to inspect and copy records, the requirement for a witness signature, and the Part 2 re-disclosure provision.]**

**[If this research encompasses mental health information, services for developmental disabilities, genetic counseling information, or if “all information in a medical record” is included, integrate the following statement regarding the right to inspect and copy:]** You are entitled to inspect and obtain copies of the mental health and developmental disabilities records that are collected as part of this study.

[Include if any of the BeyondBound locations are involved as a study site. Otherwise, omit.] During the course of this study, you might visit a BeyondBound facility for research appointments or to receive clinical services required by the study, such as laboratory tests. In such instances, you will be scheduled for these services through the BeyondBound computer system. Any clinical examination or laboratory test conducted by BeyondBound or its staff for this research will be recorded in both BeyondBounds clinical records and the study’s records.

The following healthcare providers may provide the researchers with information about you: all past and present healthcare providers, including but not limited to BeyondBound, along with its current and future affiliates.

After obtaining the health information outlined above, we may share some of this data with external offices or entities outside of BeyondBound and its clinical partners (or affiliates), such as the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information disclosed to external parties will not include your name, address, phone number, social security number, or other personal identifiers unless the release of such identifiers is necessary for their review, mandated by law, or stipulated by university policy [except that such information may be accessed by the Study sponsor and its partners or contractors at the Principal Investigator’s office].

The Entities That May Receive Your Health Information:

[Omit any sections below that are not applicable to your study.]

* Authorized personnel within BeyondBound such as administrative staff from the Office for Research, Office for Research Integrity, and members of the Institutional Review Board who may need access to your information.
* Other University research centers and contractors participating in the study,
* Study monitors and auditors tasked with ensuring the study's adherence to protocols,
* [Name of the company sponsoring the study] \_\_, the sponsor of the study, and the sponsor’s contractors and partners.
* Governmental agencies and public health authorities like the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
* Registries or other research-related databases: [Specify all registries, excluding those maintained by government agencies or public health authorities, where identifiable information will be directly disclosed by the researcher or research staff related to this study.] The specified registries include: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* [Include if HIV testing is part of the study. Otherwise, remove.] The study's physician is required to report positive HIV tests to the Nevada Department of Public Health. The Nevada Department of Public Health. maintains records of all individuals in the state with positive HIV tests. Information relayed to the IDPH includes name, social security number, current address, phone number, age, date of birth, age at diagnosis, race, ethnicity, sex, gender identity, country of birth, location at diagnosis, and the facility where the HIV or AIDS diagnosis was confirmed.
* Others: [Identify by name or category any additional individuals or organizations that may access, receive, or use the personal health information for this research study.] Additional entities or individuals with potential access to your health information include: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Please be aware that those who receive your health information may not be obligated by Federal privacy laws (like the Privacy Rule) to safeguard it. Some recipients may have the authority to disclose your information to others without obtaining your separate consent.

**[If the study involves substance use disorder information, or if "all information in a medical record" is included, incorporate the following statement regarding the Part 2 re-disclosure provision. Otherwise, omit.]**

Moreover, under federal regulations detailed in 42 CFR Part 2, there is a prohibition on the unauthorized dissemination of such records.

The findings from this investigation may be utilized for educational purposes, in scholarly publications, or presented at scientific gatherings.

**[Select the relevant expiration clause for your research, either #1 or #2]**

[#1 - Should the study encompass information on mental health, services for developmental disabilities, or if it involves "all information in a medical record," incorporate the subsequent calendar date expiration clause. If not applicable, omit.]

This consent is valid until \_\_\_\_\_\_\_. [A precise calendar date (MM/DD/YYYY) is required.] Beyond this date, BeyondBound is restricted from collecting new data about you, or from employing or sharing your health information gathered during this study for any purposes outside of the described research, without obtaining further consent from you. Illinois State Law allows the use and sharing of your mental health data strictly as outlined in this document.

 Or

[#2 - If your research does not pertain to mental health data, services for developmental disabilities, or "all information in a medical record," then include a termination date or event pertinent to the individual or the objective for using or sharing Personal Health Information. It's worth noting that "completion of the research study" or "indefinite" may be deemed acceptable for the use or disclosure for research purposes. If irrelevant, omit the following clause.

Your consent remains valid until \_\_\_\_\_\_\_ without your revocation.

You retain the right to withdraw consent for participation in this study at any moment and through any means, although revocation of authorization for the use or disclosure of your health information must be in writing. [If mental health data is involved: The revocation document should bear your signature and that of the witness to your signing, if not, omit this part]

To withdraw your authorization, please contact:

[All the following details must be filled in.]

Principal Investigator’s Name:

Institution:

Department:

Address:

You are not obliged to permit the use or sharing of your health information; nevertheless, refusal will preclude your participation in this research endeavor. Declining to authorize the use or disclosure of your health information will not impact your care from healthcare providers, nor will it influence your dealings with health plans in terms of payments, enrollment, or eligibility for benefits.

[This section is mandatory for research conducted at BB’s affiliated medical institutions Omit if not applicable.] A duplicate of this signed consent form, details pertaining to this research, and outcomes of any tests or procedures conducted may be documented in your medical records. This information might be accessible to your insurance provider.

[Important: If your research is subject to the GDPR, you are required to insert a page break here and incorporate the provisions from the GDPR Compliant Consent Template (HRP-590), or develop a supplementary document adhering to the GDPR Compliant Consent Template and annex it to this consent form.

Should you have any inquiries, issues, or grievances, you are encouraged to reach out to the Principal Investigator [Insert Name and either contact number or email here], or [mention another investigator, such as a student, if applicable]. [For studies conducted internationally, make sure to include the international dialing code for the study team’s contact numbers, along with the contact details of any local partners.]

This study has undergone scrutiny and received approval from an Institutional Review Board (IRB) – an entity committed to safeguarding the rights and welfare of individuals participating in research endeavors. If you find yourself in any of the following situations, you are advised to get in touch with the IRB directly through phone at (646) 217-0403or via email at info@beyondbound.org:

* If the research team has not addressed your queries, issues, or complaints to your satisfaction.
* If you are unable to make contact with the research team.
* If you wish to speak with someone other than the research team.
* If you have questions regarding your rights as a participant in this study.
* If you seek further information about this study or wish to offer feedback.

Optional Components:

[This section should be included only if there are optional aspects of the research. If not applicable, please remove.] Certain aspects of this study are voluntary, indicating that your consent to these elements is not required for your participation in the main research project. To express your agreement to partake in these optional activities, kindly mark your initials beside each listed activity.

Example Optional Components

| Consent | Decline |  |
| --- | --- | --- |
| \_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_ | The researcher is permitted to utilize [indicate specific type of recordings: audio, video, and/or images] featuring me for academic purposes or publications, where revealing my identity through visual or auditory means could contribute to a better comprehension of the research by others. My identity may be disclosed through this process. |
| \_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_ | The researcher is authorized to retain my contact details for future communication, to inquire about my potential interest in engaging in subsequent studies conducted by the Principal Investigator. |
|  |  |  |

NOTE: Provided below are the signature sections for both the consent form and the HIPAA Authorization. The initial signature section should be utilized when the participant is signing the consent and HIPAA Authorization form. Additionally, there are signature sections for various consent/Authorization scenarios below. **Please select the signature section(s) that are relevant to your study and remove any that are not applicable**. Should your study have different formats in which consent will be obtained, it is necessary to submit a consent form tailored to each specific method employed to document consent.

**A signature from a witness is mandated for research that involves accessing mental health information from the participant’s medical records or if the consent form specifies that “all information in a medical record” is the type of data being accessed.**

**When securing the signature of the participant:**

**Signature for Adults 18 or Older Able to Provide Consent**

By signing, you grant your consent to participate in this research and authorize the access, use, and disclosure of your personal health information from your medical records for the aims of this study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent

**For Electronic Consent** (akin to written consent but acquired via an electronic platform):

To ensure the acquisition of valid consent, it's essential to secure a verified electronic signature. The electronic consent form should include spaces for participants to type their name and the current date, thereby formalizing their consent electronically.

**Signature Requirement for a Witness in Cases Involving Mental Health Information:**

**For research that involves accessing information pertaining to mental health or services for developmental disabilities from a participant’s medical records, or if the consent document specifies that “all information in a medical record” will be accessed, the inclusion of a witness's signature is obligatory. This section should be omitted if it does not apply.**

**The consent document must be signed by the individual who is legally authorized to give consent. Furthermore, this signature must be witnessed by someone who can verify the identity of the consenting individual (it should be noted that the ‘witness’ required on the consent form might not necessarily be the same individual from the study team who is designated to ‘obtain’ consent, depending on whether there is a pre-existing relationship and/or specific procedures in place that ensure the verification of identity).**

I affirm that the identity of the person providing consent has been confirmed.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Individual Witnessing the Consent Process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Witness to the Consent Process

**Signature Block for Participants with Limited Decision-making Ability**

In situations where adults are unable to consent (for example, persons with limited decision-making abilities, non-literate English speakers, or during an emergency scenario), directly securing truly informed consent may not be feasible. In such instances, the IRB may permit consent to be given by the individual’s legally authorized representative. Efforts should be made to gain the assent of the study participant as much as possible. For additional details regarding the engagement of legally authorized representatives, refer to the standard operating procedures of BeyondBound on Legally Authorized Representatives, Minors, and Guardians (HRP-013). Your study protocol must detail any intentions to include individuals lacking the capacity to consent, and the following signature block must be utilized when consent for participation in the study is to be obtained through a legally authorized representative:

Your signature affirms your consent for the individual specified to participate in the study.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant (Print)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Legally Authorized Representative's Signature Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Legally Authorized Representative (Print) Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Individual Responsible for Consent Collection Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Individual Responsible for Consent Collection (Print) Date